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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	6

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/750,031	SIEMENSMA ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
18)☐ Interview Summary (PTO-413) Paper No(s). _____
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other.

DETAILED ACTION

Oath/Declaration

1. The oath or declaration appears questionable as to the inventors' names. There is confusion as to what is the correct name of inventor Antonius Wagenmakers. In two separate declarations, the inventor's name appears as Antonius A. J. Wagenmakers and Antonius J. M. Wagenmakers. Further, Andries Siemensma appears as both Andries D. Siemensma and Andries Dirk Siemensma. Appropriate correction and/or clarification is requested.

Claim Objections

2. Claims 4, 6 – 7 and 9 – 16 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend from any other multiple dependent claim. See MPEP § 608.01(n).

3. Claim 13 is objected to for containing minor informalities. The term "vitamines" should be correctly spelled "vitamins."

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims15 and 16 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a

process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 – 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are rendered vague and indefinite for reciting "an amount of at least one additional free amino acid" because it is not clear to what "an amount" extends, and it is not clear if the composition already contains free amino acids as the claim recites "additional" free amino acids.

In claim 11, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 11 is further confusing because it is not clear to what "mono" or "di" refers, as these are simply prefixes which, do not appear to have any meaning as written. It is noted, that the phrase or term "mono oligosaccharide" is an oxymoron and has no meaning in the art.

Claim 13 is rendered vague and indefinite for reciting "components having co-enzyme and antioxidant properties" because the phrase does not clearly delineate the invention as to what applicant regards as the invention. Further, the phrase is not adequately defined by the claim language or specification.

Claim 13 is further indefinite for reciting "including emulsifiers" because it is not clear if the limitation, emulsifiers, is part of the claimed invention. For example, does the composition comprise any lipid, any emulsifier, or both?

7. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). The use of a preference in claim language is vague, indefinite and fails to particularly point out what applicant regards as the invention.

In the present instance, claim 3 recites the broad recitation "0.2 – 20 wt %", and the claim also recites "preferably 1 – 10 wt %" which is the narrower statement of the range/limitation.

Claim 9 recites the broad recitation "2 – 40 amino acids", and the claim also recites "preferably 3 – 20 amino acids" which is the narrower statement of the range/limitation.

Claim 10 recites the broad recitation "0.1 – 50 wt %" as well as "preferably 2 – 25 wt %" which is the narrower range.

Claim 12 recites the broad recitation "10 – 90 wt %" and also recites "preferably 50 – 80 wt %" which is the narrower statement of the range/limitation.

8. Claims 15 and 16 provide for the use of the composition of claims 1 - 14, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1 –2, 4, 6 – 7, 11, 13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilbert et al. (US 5,776,887).

Applicant claims a composition comprising carbohydrate material, peptide material and at least one additionally free amino acid selected from leucine or phenylalanine, wherein the peptide material is derived from wheat, rice, pea, casein or whey proteins via hydrolysis and the

carbohydrate material is one of monosaccharide, disaccharide or oligosaccharide. Applicant further claims the composition wherein both leucine and phenylalanine are present as well as arginine or glutamine. The compositions further contain vitamins, flavors, minerals, lipids, proteins and components with antioxidant and/or coenzyme activity and can be used in enteral clinical feeding.

Wilbert et al. teach nutritional compositions comprising a carbohydrate, fat and protein component (col.1 line 60 – col.2 line 15) wherein additional free amino acids selected from leucine, phenylalanine, arginine and glutamine (col.4 line 19-22) are added. The protein, or peptide material is hydrolyzed from whey or casein protein (col.4 line 22-26) and the carbohydrate is selected from monosaccharides, disaccharides and polysaccharides (col.2 line 1-11). The nutritional compositions of Wilbert et al. further contain vitamins (including vitamins C and E, which are antioxidants, see examples), minerals (col.4 line 44-46), emulsifiers (col.5 line 11-12), flavors (col.5 line 19-21) and lipids (col.3 line 60-65). Wilbert et al. teach the compositions wherein they are liquid enteral formulations (col.5 line 39-41) utilized for clinical purposes (abstract).

The reference anticipates the claimed subject matter.

11. Claims 1 – 2, 4, 6 – 7, 9 – 11, 13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kahn et al. (EP 0 421 309 A2).

Applicant claims a composition comprising carbohydrate material, peptide material and at least one additionally free amino acid selected from leucine or phenylalanine wherein the carbohydrate material is one of monosaccharide, disaccharide or oligosaccharide and the peptide

material is derived from wheat, rice, pea, casein or whey proteins via hydrolysis. The peptide materials have an average peptide chain length of 2 – 40 amino acids and are present in amounts of 0.1 – 50 wt %. Applicant further claims the composition wherein both leucine and phenylalanine are present as well as arginine or glutamine. The compositions further contain vitamins, flavors, minerals, lipids, proteins and components with antioxidant and/or coenzyme activity and can be used in enteral clinical feeding.

Kahn et al. teach compositions containing casein and/or soy protein hydrolysates combined with whey protein hydrolysates and amino acids (abstract) wherein the hydrolysates are obtained by hydrolysis of the protein (p.2 line 15-20). The whey protein hydrolysate comprises amino acids as oligopeptides having 4 – 10 amino acids (p.4 line 5-10). The amino acids are in free form and comprise less than 3.5 % by weight (p.5 line 14-20) and include arginine, glutamine, leucine and phenylalanine (p.8 line 30-50). The composition further includes carbohydrates (particularly maltodextrines p.6 line 8-9), fatty acids, vitamins, minerals (p.5 line 54-56) and flavoring agents (p.6 line 53). Sources of fatty acids are triglyceride oils and phospholipids (p.6 line 25), vitamin sources include vitamins A, B6, B12, C (antioxidant), D and K and trace minerals include calcium, sodium, phosphorous and potassium (p.6 line 43-49). The compositions are disclosed for enteral use as well as aqueous liquids, food supplements, complete diet and therapeutic nutrition (p.6 line 12-19).

The reference anticipates the claimed subject matter.

12. Claims 1 – 2, 4, 6 – 8, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kingham (WO 95/22909).

Applicant claims a composition comprising carbohydrate material, peptide material and at least one additionally free amino acid selected from leucine or phenylalanine wherein the carbohydrate material is one of monosaccharide, disaccharide or oligosaccharide and the peptide material is derived from wheat, rice, pea, casein or whey proteins via hydrolysis. Applicant further claims the composition wherein both leucine and phenylalanine are present as well as arginine or glutamine. The compositions further contain vitamins, flavors, minerals, lipids, proteins and components with antioxidant and/or coenzyme activity.

Kingham teaches nutritional compositions containing a carbohydrate, a protein (or peptide material) and amino acids selected from arginine, phenylalanine and leucine (abstract). Carbohydrates include monosaccharides, disaccharides and polysaccharides such as dextrose, maltose, sucrose and maltodextrines (p.6). The protein source is selected from wheat, peas, beans, and milk (casein, whey) and is in the hydrolyzed form (p.8). The composition additionally contains a fat component wherein the fat is phospholipids or sterols (p.10), vitamins, minerals, flavoring agents, emulsifiers, beta carotene (antioxidant), and preservatives (p.12). Example 4 teaches a composition containing maltodextrine, sugar, dextrose, hydrolyzed gelatin, lecithin, vanilla flavoring and a vitamin/mineral mix wherein arginine, phenylalanine and leucine are represented. Example 5 teaches a composition containing dextrose, maltodextrin, sugar, oils, hydrolyzed gelatin, vitamin/mineral mix, lecithin, flavoring and citric acid (antioxidant) wherein arginine, phenylalanine and leucine are represented.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1 – 5, 12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kingham et al (WO 95/22909) in view of (Berthelsen et al. (WO 97/39641).

Applicant claims a composition comprising carbohydrate material, peptide material and at least one additionally free amino acid selected from leucine, phenylalanine or both wherein the amino acids are present in amounts of 0.2 – 20 wt. %. Applicant further claims the composition additionally comprising arginine or glutamine wherein these amino acids are present in amounts of 0.1 – 20 wt. %. The carbohydrate material is present in amounts of 10 – 90 wt % and the

composition is in the form of an isotonic sports drink or sports bar utilized during or after physical exercise.

Kingham teaches nutritional compositions containing a carbohydrate, a protein (or peptide material) and amino acids selected from arginine, phenylalanine and leucine (abstract). Carbohydrates include monosaccharides, disaccharides and polysaccharides such as dextrose, maltose, sucrose and maltodextrines (p.6). The protein source is selected from wheat, peas, beans, and milk (casein, whey) and is in the hydrolyzed form (p.8). The composition additionally contains a fat component wherein the fat is phospholipids or sterols (p.10), vitamins, minerals, flavoring agents, emulsifiers, beta carotene (antioxidant), and preservatives (p.12). Example 4 teaches a composition containing maltodextrine, sugar, dextrose, hydrolyzed gelatin, lecithin, vanilla flavoring and a vitamin/mineral mix wherein arginine, phenylalanine and leucine are represented. Example 5 teaches a composition containing dextrose, maltodextrin, sugar, oils, hydrolyzed gelatin, vitamin/mineral mix, lecithin, flavoring and citric acid (antioxidant) wherein arginine, phenylalanine and leucine are represented.

Kingham does not teach the composition in the form of an isotonic sports drink or bar for use during or after physical exercise. However, at the time of the invention, one of ordinary skill in the art would have been motivated to do so because Berthelsen et al. teach an isotonic fluid used during or after physical exercise (p.3) wherein the beverage contains a protein hydrolysate of an animal or vegetable origin (abstract). Berthelsen et al. teach an energy supplement in the form of a beverage wherein a protein hydrolysate from whey, casein, pea or wheat (p.2 line 28-32) obtained via hydrolysis (p.3 line 5-8), are combined with carbohydrates such as maltodextrines, glucose or sucrose (p.3). It would have been obvious to one of ordinary skill in

the art at the time of the invention to form the composition of Kingham et al. as an isotonic sports drink for the reasons above.

The above references do not teach the compositions with specific percents of amino acids or carbohydrates. However, it would have been obvious to one of ordinary skill in the art to optimize quantities and volumes of known ingredients because it was routine practice in the art at the time of the invention. One of ordinary skill in the art would have been motivated to optimize the compositions of Kingham with a reasonable expectation of success for obtaining a nutritional composition, because of the known benefits and functions of each ingredient as disclosed by the above references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

June 21, 2001

LEON B. LANKFORD, JR.
PRIMARY EXAMINER